

REMARKS

This Response responds to the Office Action dated February 22, 2006. No claims are cancelled or added. As a result, claims 1-20 are pending in this patent application.

1. Real Party In Interest

The real party in interest of the above-captioned patent application is the Assignee, Cardiac Pacemakers, Inc.

2. Related Appeals and Interferences

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in an appeal of this matter.

3. Status of the Claims

Claims 1-20 are currently pending in this patent application. A Final Office Action was mailed on February 22, 2006. Claims 1-20 stand finally rejected and their rejection is the subject of the appeal of this matter.

4. Status of Amendments

No claims have been amended.

5. Summary of Claimed Subject Matter

Independent method claim 1 relates to displaying status information of a patient's heart rhythm by providing a cardiac rhythm management device (*see, e.g.*, Application at FIG. 2 at 10) with deadfront status indicator lamps (*see, e.g.*, Application at FIG. 2 at 26, 28, 30, 32), where each lamp 26, 28, 30, 32 includes an icon that can be illuminated for viewing (*see* Application at page 5, lines 18-22). After querying an implantable device (*see, e.g.*, Application at FIG. 1 at 3) and receiving status information from the implantable device 3, the cardiac rhythm management device 10 displays the status using the status indicator lamps 26, 28, 30, 32.

Independent method claim 13 relates to displaying status information of a patient's heart rhythm by providing a cardiac rhythm management device (*see, e.g.*, Application at FIG. 2 at 10) with deadfront status indicator lamps (*see, e.g.*, Application at FIG. 2 at 26, 28, 30, 32). After querying an implantable device (*see, e.g.*, Application at FIG. 1 at 3) and receiving status information from the implantable device 3, the cardiac rhythm management device 10 displays the status using the status indicator lamps 26, 28, 30, 32.

Independent method claim 1 relates to displaying status information of a patient's heart rhythm by providing a cardiac rhythm management device (*see, e.g.*, Application at FIG. 2 at 10) with deadfront status indicator icons (*see, e.g.*, Application at FIG. 2 at 26, 28, 30, 32; *see* Application at page 5, lines 18-22) and a button (*see, e.g.*, Application at FIG. 2 at 24) on a case (*see, e.g.*, Application at FIG. 2 at 12). Activation of the button 24 initiates communication between the cardiac rhythm management device 10 and an implantable device (*see, e.g.*, Application at FIG. 1 at 3). During the communication, the cardiac rhythm management device 10 receives information and in response, illuminates at least one of the deadfront status indicator icons 26, 28, 30, 32 to visually communicate the information to the patient.

6. Grounds for Rejection to Be Reviewed on Appeal

- 1) Was a *prima facie* case of obviousness under 35 U.S.C. § 103(a) properly made with respect to claims 1-21 using Hoffman (U.S. Patent No. 6,622,017) in view of Lai (U.S. Publication No. 2005/0020308) in further view of Boveja (U.S. Patent No. 6,879,859)?

7. Argument

A) *The Applicable Law*

The Examiner also has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988). In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the

references. *Id.* The M.P.E.P. contains explicit direction to the Examiner that agrees with the *In re Fine* court:

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *M.P.E.P.* § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d (BNA) 1443 (Fed. Cir. 1992). However, while it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). The requirement of a suggestion or motivation to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Sang Su Lee*, 277 F.3d 1338; 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002), which notes that the motivation must be supported by evidence in the record.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). References must be considered in their entirety, including parts that teach away from the claims. See MPEP § 2141.02. The fact that references can be

combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01.

B) The References

Stanton: describes a patient programmer for facilitating control over an implanted medical device that provides tactile, audible, and visible feedback to the user to convey information regarding the operation of the programmer and the implanted device (*see Stanton at Abstract*). The programmer can include a beeper and light-emitting diodes (LEDs) to indicate the status of the programmer or the implanted device (*see Stanton at Abstract; FIG. 3*).

Nappholz: describes an external device used to control the operation of a pacemaker (*see Nappholz at Abstract*). The external device has a speaker and a display to provide audible and textual alerts and information related to the operation of the pacemaker (*see Nappholz at col. 9, lines 53-59*).

C. Discussion of the Rejections

C.1 The Rejection of claims 1-20 using Stanton in view of Nappholz.

Appellant respectfully submits that there is no *prima facie* case of obviousness of claims 1-20 because (1) Stanton and/or Nappholz fail to disclose, teach, or suggest all elements of the present claims; and (2) there exists no motivation to combine these references in the manner used in the rejection.

In particular, Appellant cannot find in the cited portions of these references any disclosure, teaching, or suggestion of "deadfront status indicator lamps each including a deadfront icon that is illuminated for viewing on a front of the case" as recited in claim 1 and similarly recited in claims 13 and 18. Instead, Stanton apparently merely describes the use of LEDs to indicate whether a particular programming event has occurred (*see Stanton at col. 14, lines 47-53*). Several LEDs are apparently arranged with corresponding text on the body of the programmer to indicate various states or other status information regarding the implanted pulse generator (IPG) or the programmer (*see Stanton at FIG. 3 at 32, 34, 36, 38*). There is no indication that the LEDs in Stanton are used to illuminate an icon or other symbolic picture. Instead, the LEDs are simply exposed to the user to provide a binary state indication (e.g., on or

off) (*see* Stanton at col. 6, lines 26-37). Moreover, Nappholz fails to disclose, teach, or suggest such use of LEDs to illuminate icons. The device described in Nappholz uses a display (*see* Nappholz at FIG. 5 at 66) to provide status and other information (*see* Nappholz at col. 6, lines 49-50; col. 9, lines 53-59). The use of such a display obviates any need for LEDs. Thus, neither Stanton nor Nappholz provide disclosure of the claimed elements.

Moreover, Appellant respectfully submits that the references provide absolutely no motivation to combine Stanton with Nappholz. The Final Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). However, the Final Office Action merely asserts:

... it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Stanton et al. to include various warning/issue indicators to provide messages to a patient...

(Final Office Action at page 3). Appellant respectfully disagrees with this vague and conclusory assertion, which is unsupported by any objective evidence. One of ordinary skill in the art certainly would not attempt to “improve” Stanton in this manner. As discussed above, Stanton apparently describes a system that includes “various warning/issue indicators to provide messages to a patient.” However, in contrast to the illuminated icons that the present application describes, Stanton’s device uses bare LEDs that provide a binary indication (on/off) or blink in patterns to reflect IPG status (*see* Stanton at col. 14, line 47 to col. 15, line 6). Applicant cannot find anything in Stanton indicating recognition of any limited usefulness of bare LEDs. One of ordinary skill in the art would not necessarily look to improve Stanton’s indicators as Stanton already provides indicators in one form—without any recognition of the shortcomings of such indicators.

Furthermore, even in the case of someone attempting to improve Stanton, one would not look to Nappholz to improve Stanton in this area. First, Stanton’s device, which uses LEDs, is arguably sufficient for its very basic intended purpose; no objective evidence of record suggests that one should look to improve Stanton with a display as described in Nappholz. Finally, while an automobile may indeed include an example of a deadfront status indicator, as indicated by the

Final Office Action (*see* page 3), Appellant respectfully submits that this does not imply that one of ordinary skill in the medical device field would look to an automobile to “improve” the device disclosed in Stanton, particularly where there is no objective evidence of record of any recognition in the art of any serious limitation of the device of Stanton. Instead, the rejection’s asserted “motivation to combine” appears to be nothing more than the use of impermissible hindsight based on Appellant’s application to justify such a combination.

8. Summary

In sum, because the cited combination of Stanton and Nappholz fail to set forth all elements recited or incorporated in the present claims and because no evidence of any motivation or suggestion to combine the references has been objectively established, Appellant respectfully submits that there is no *prima facie* case of obviousness of claims 1-20. Therefore, Appellant respectfully requests reversal of all bases of rejection of all claims.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Serial Number: 10749,093

Dkt: 279-B31US2

Filing Date: December 17, 2003

Title: PATIENT CONTROLLED THERAPY MANAGEMENT AND DIAGNOSTIC DEVICE WITH HUMAN FACTORS
INTERFACE

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD E. STEIN ET AL.

By their Representatives,

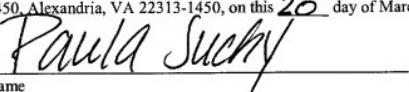
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of March, 2006.

Name 

Signature 